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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/551,898
Filing Date: January 05, 2006
Appellant(s): MORIWAKI ET AL.

Kuniharu Moriwaki, Susumu Hongo, Takafumi Kiyono
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12 April 2010 appealing from the Office action mailed 23 November 2009

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1 and 4-7 are rejected.

Claims 1 and 4-7 are pending.

Claims 2 and 3 were cancelled during prosecution.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,762,632 Whisson 6-1998

Teraoka, Yosisuke. "Winged injection needle device." EP 1048311 A2. (2.11.2000)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application EP 1 048 311 A2 to Yosisuke Teraoka (Teraoka) in view of U.S.Patent

5,762,632 to Maxwell Edmund Whisson (Whisson).

In regards to claim 1, Teraoka teaches a medical needle device with a winged shield (Fig. 1, #1) comprising a winged shield (Fig. 1, #7 & 8), that has a substantially cylindrical shield tube (Fig. 1, #8) an a pair of wings (Fig. 1, #7), a hub that is inserted into an inner bore of the shield tube so as to be movable in an axial direction (col. 2, lines 22-27), a needle that is mounted to a front end of the hub (Fig. 1, #3), a rear end of the hub capable of being connected with an infusion tube (col. 7, lines 43-44) and a tip of the needle capable of being stored in the inner bore of the shield tube (col. 2, lines 26-27), the needle is inserted into and coupled with a bore of the hub at a front end thereof (Fig. 5, #11, 12 – shows the needle 11 inserted into the hub 12).

But Teraoka does not teach wherein at least a part of the hub is made of a material having flexibility, wherein that the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube and is latched to shield tube.

Whisson teaches wherein at least a part of the hub is made of a material having flexibility (col. 2, line 36), wherein the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube (Fig. 6 shows the extended position of the needle & col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable) and is latched to the shield tube (col. 4, lines 24-28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the flexible delivery tube and the flexible duct of Whisson as a hub and

a shield tube, respectively, in the medical needle of Teraoka in order to allow for destructive bending or "kinking" of the delivery tube to render the infusion set incapable of further use (col. 4, lines 61-64) as explicitly taught by Whisson.

In regards to claims 4-7, Teraoka, as modified by Whisson teaches the medical needle device according to claim 1 (see rejection above), and further teaches:

Claim 4: the shield tube is made of material having flexibility (Whisson col. 3, lines 11-16 — a flexible delivery tube within a flexible tubular duct are bendable, the flexible tubular duct is a part of the shield tube);

and Teraoka further teaches:

Claim 5: wherein the shield tube (Fig. 1, #8) includes an extendable portion that is structured to be extendable and contractible (col. 5, lines 24-27), the needle can be moved in the axial direction of the shield tube by extending and contracting the extendable portion (col. 5, lines 27-29) and the shield tube and the hub are bendable at the extendable portion (implied the shield tube, as modified by Whisson, is flexible, the extendable portion of Teraoka is flexible otherwise it could not be extendable thus both are bendable);

Claim 6: wherein the extendable portion has a plasticity-process accordion-like structure (col. 5, lines 31-35);

Claim 7: when the shield tube and the hub in the inner bore of the shield tube are bent together, a minimum radius of curvature at a bent part can be 3 mm or smaller (implied in the flexible nature of the fluid delivery tube that holds the needle, as modified by Whisson, and the bendable accordion structure of the extendable member

is capable of bending 3 mm or smaller, furthermore it would have been obvious to one of ordinary skill in the art to chose materials that would optimize the curve to allow the patient a greater range of motion such that conscious and unconscious movement does not remove the needle or damaging the vein. See MPEP 2144.05 II A - Optimization of ranges).

(10) Response to Argument

Regarding Applicant's Argument A: Teraoka and Whisson, taking alone or together, fail to teach or suggest all the features of claim 1 (Appeal Brief Pg. 4).

The requirement for claim 1 is "a shield tube and hub to be bendable together at least in a part of a range along an axial direction when a needle protrudes from a front end of the shield tube and is latched to the shield tube so as to be in a puncturing position" (Appeal Brief pg. 4).

Plastics, such as those commonly used with needle infusion sets are bendable in at least some fashion, even rigid plastics are bendable to a degree before plastic deformation. Teraoka discloses the device is made of plastics, and does not set forth particular limitations of the type of plastics or the characteristics, except for the flexibility of the accordion structure and the hardness, which is different from rigidity and resistance to flexure, of the protector (See at least: Teraoka col. 4, lines 49-50, 54, col. 6, lines 37-43). How bendable a material is depends on the desired properties, such as extensibility or flexibility, which is discussed by Whisson, regarding the extensibility of the flexible delivery tube (Whisson col. 2, lines 63-65).

Applicant argues that the modification of Teraoka with the flexible delivery tube of Whisson would render Teraoka inoperable for its intended purpose (Appeal Brief pg. 5).

Applicant then goes on to say that an intended purpose of Teraoka is to "allow an effective and precise control of the Teraoka injection needle during insertion or removal" which would be rendered inoperable because the flexible delivery tube and flexible duct of Whisson would not adequately transfer force to cause insertion of the needle (Appeal Brief pg. 6). This argument is not persuasive, because the intended purpose of Teraoka is to protect users from needle stick injuries (Teraoka para. 2, para. 7) and the precise control feature is merely a description of the design considerations of the protector tip opening 11.

Applicant further argues that the opening 11 of the protection tip must be large enough to allow the needle to slide freely, implying that this would not be sufficient to hold the needle in position during insertion, if inserted as taught by Whisson (col. 4, lines 46-49). However, Teraoka states in para. 30, "...the injection needle 2 is stuck into a patient's body while holding the wing 7 so as to administer the liquid solution into the patient body after sticking...", indicating that the wings are used to stabilize and push the needle into the patient's skin. Thus, modifying the needle hub of Teraoka with the flexible delivery tube of Whisson would not render Teraoka unsuitable for its intended purpose because the purpose is the same as Whisson, to prevent accidental needle stick injuries, and furthermore, Teraoka is inserted into the body in much the same way as Whisson (col. 4, lines 46-49).

While Teraoka teaches that the opening is large enough to allow the needle to slide freely, Teraoka also teaches in para. 24, that the protector tip 10 is tapered so that the needle does not move during inserting, and para. 29 states that the diameter of the pore 11 of protector 10 be between 1.1 to 2.0 times the diameter of the needle, such that the needle does not move during sticking, and so that the needle slides freely to allow covering after use. Teraoka is teaching that

the pore size must be balanced between large enough to allow freely sliding movement, but small enough to prevent excessive lateral movement during penetration.

Applicant also argues, that the protector 8 of Teraoka does not appear to be bendable, however Teraoka is silent on whether or not the protector is bendable, only stating that the hardness is sufficient to protect and retain the needle (para. 28). Applicant continues, "even assuming arguendo the protector 8 is bendable, modifying the protector 8 and the holder 3 to make them bendable together would cause the injection needle to 2 to bend and as a result render the injection needle device 1 inoperable for its intended purpose" (Appeal Brief pg. 6). The claims require that the shield tube and hub be bendable together "at least in a part of a range…when the needle protrudes from the front end and latched to the shield tube". As shown, when combined with Whisson the flexible delivery tube is attached to the needle forming the needle holder, and the flexible delivery duct allows the bending when the needle is extended and latched in the penetrating position as shown in the office action (pgs. 2-3).

Regarding Applicant's Argument B: The discussion of "the movement of the engaging means to the retracted position may cause a destructive bending or 'kinking' of the delivery tube to render the infusion set incapable of further use" in Whisson would not suggest including the flexible delivery tube and the flexible duct of Whisson as a hub and a shield tube, respectively, in the injection needle of Teraoka.

Whisson teaches an infusion set, and defines an infusion set as "a base…, a hollow needle...and a flexible delivery tube... the other end of the flexible delivery tube being adapted to be connected to a receptacle or delivery means" (col. 1, lines 4-11) and goes on to state the purpose of the invention is "to provide an infusion set which on completion of its use can be

rendered safe" (col. 1, lines 30-31) which is the same purpose as Teraoka (para. 7). Whisson keeps the flexible tube, much like a pre-packaged infusion set with butterfly needle would include a flexible tube, but Whisson also wants to render the flexible infusion set safe because "after the user has removed the line from the vein of a patient the needle is usually held such that it is suspended from the flexible delivery tubing and is able to move in an unpredictable manner due to the flexible resilient nature of the flexible delivery tubing" (col. 1, lines 14-19).

One of ordinary skill, with the infusion set of Teraoka, and knowledge from the specification of Whisson would be motivated to use a flexible delivery tube of Whisson because Teraoka has a flexible resilient tube 4 that would suffer from the same problem of unpredictable movement. Since flexible tubes can kink in extreme bends, Whisson would suggest using the flexible delivery tube and shield to render the infusion set unsuitable for later use, which would satisfy the purpose of Whisson and Teraoka of providing a safe and easily contained injection needle to prevent needle stick injuries.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/L. R. W./

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Sue Lao/

Primary Examiner